REMARKS

Claims 1-26 are pending in the application.

Claims 1, 3-17 and 22-26 are rejected under 35 U.S.C. § 102(e). Claim 2 is rejected under 35 U.S.C. § 103(a). Claims 18-21 are rejected under 35 U.S.C. § 103(a).

Any reference to the "Office Action" or "Non-Final Office Action" here refer to the Non-Final Office Action dated November 6, 2007.

Claim Rejections – 35 U.S.C. § 102

<u>Claims 1, 3-11</u>

Claims 1 and 3-11 are rejected under 35 U.S.C. § 102(e) as being anticipated by Baura et al (USPN 6,561,986)(Baura). Without conceding the assertions in the Non-Final Office Action, applicants amend independent claim 1 herein to more clearly recite the scope of what applicants consider to be their invention.

Amended independent claim 1 recites in part:

> deriving . . . two or more electrical bio-impedance values *indicating the electrical bio-impedance of body tissues and* fluids within a region of the anatomical space; *and analyzing the two or more electrical bio-impedance values* for indications of fluid movement, accumulation, or depletion affecting the region. (Emphasis provided)

One having skill in the art will recognize that Baura fails to disclose the limitations of applicants' amended independent claim 1, and that the rejection of independent claim 1 under 35 U.S.C. § 102(e) is herein traversed by applicants.

In the section of Baura cited and relied upon in the Office Action (entitled "Apparatus for Hemodynamic Assessment"), Baura describes an exclusive intent to determine a thoracic impedance, and to achieve that end, describes an intent to eliminate from the impedance measurement the overlying impedance values contributed by skin and tissue:

> Typical impedance associated with a human subject's skin is 2 to 10 times the value of the underlying thoracic impedance Z.sub.T (t). *To aid in eliminating the contribution from skin and tissue impedance*, the apparatus of the present invention uses at least two, and typically four electrode arrays 1202a-d for measurement. (Col. 20, lines 25-30)(Emphasis provided)

Baura then describes eliminating the skin and tissue impedances to obtain the thoracic impedance.

> Current flows from each stimulation electrode terminal 1221 through each constant skin impedance, Z_{sk1} or Z_{sk4}, each constant body tissue impedance,

> Z_{b1} or Z_{b1}, and each constant skin impedance, Z_{sk2} or Z_{sk3}, to each measurement electrode terminal 1223. The voltages at the measurement electrode terminals 1223 are measured and input to a differential amplifier circuit 1227 within the preprocessor 1206 to obtain the differential voltage, $V_T(t)$. *The desired thoracic impedance*, $Z_T(t)$, *is then obtained* using the relationship of Eqn. 30. (Col. 20, lines 38-47)(Emphasis provided)

Hence, skin and tissue impedances are neither derived nor analyzed in Baura. Rather, a total impedance value is obtained for a current passed through each stimulation/ measurement electrode pair, and the skin and tissue impedances are then filtered out and discarded by a differential amplifier circuit to obtain the objective of Baura, the "desired thoracic impedance"..

Baura states that "the apparatus is adapted for the measurement of the cardiac output of a human being, although . . . other hemodynamic parameters and types of living organism may be evaluated in conjunction with the invention" (Col. 19, lines 34-38). In particular, Baura lists other hemodynamic parameters "such as the pre-ejection period (PEP, the interval between Q point and B point), isovolumetric relaxation time, presence of excess intravascular fluid, presence of excess pulmonary fluid and the like", and that the hemostatic parameters are "not limited to the measurement of stroke volume, cardiac output, or QRS complex identification", (Col. 8, lines 8-13).

However, according to the express language of Baura, such "other hemodynamic parameters" must be derivable solely from the "desired thoracic impedance" measurement, and not from a measurement including skin and/or tissue impedances. Inasmuch as no embodiment of Baura includes or involves the use of the skin and tissue impedances eliminated according to Baura's express disclosure, Baura fails to disclose applicants' recited claim limitation of:

> deriving . . . two or more electrical bio-impedance values *indicating the electrical bio-impedance of body tissues and* fluids within a region of the anatomical space; *and analyzing the two or more electrical bio-impedance values* for indications of fluid movement, accumulation, or depletion affecting the region. (Emphasis provided).

For at least the reasons provided, applicants respectfully submit that amended claim 1 is patentably distinct from and allowable over Baura, and request withdrawal of the 35 U.S.C. § 102(e) rejection therefrom. Inasmuch as claims 3-11 depend from and incorporate the distinguishing limitations of independent claim 1, applicants likewise request withdrawal of the 35 U.S.C. § 102(e) rejections from claims 3-11.

Claims 12-17, 22-26

Claims 12-17 and 22-26 are also rejected under 35 U.S.C. § 102(e) as being anticipated by Baura et al (USPN 6,561,986). Without conceding the assertions presented in the Office Action, independent claim 12 is amended herein to recite:

> processor circuitry programmed with instructions configured when executed to . . . compute from each of different pairs of the injection and measurement vectors an electrical bio-impedance value that characterizes the electrical bio-impedance of the mammalian *tissue and* fluids in a region of an anatomical space, *and to analyze the electrical bio-impedance values* and identify characteristics indicating fluid movement, accumulation, or depletion affecting the region. (Emphasis provided)

For at least the same reasons discussed regarding amended independent claim 1, applicants respectfully submit that Baura does not disclose "processor circuitry programmed with instructions configured when executed to . . . compute . . . an electrical bio-impedance value that characterizes the *electrical bio-impedance of the mammalian tissue* . . . and to analyze the electrical bio-impedance values". Applicants respectfully submit that amended claim 12 is patentably distinct from and allowable over Baura, and request withdrawal of the 35 U.S.C. § 102(e) rejection therefrom. Inasmuch as claims 13-17 and 22-26 depend from and incorporate the distinguishing limitations of independent claim 12, applicants likewise request withdrawal of the 35 U.S.C. § 102(e) rejections from claims 13-17 and 22-26.

Claim Rejections – 35 U.S.C. § 103

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baura as applied to claim 1 above, and further in view of Takehara et al (US2002/0022787)(Takehara) in view of Duong et al (USPN 6,740,518)(Doung).

However, applicants submit that Takehara cannot be properly combined with Baura. Such combination would render Baura unsuitable for its intended purpose and would improperly change the principle of operation of Baura, and Baura expressly teaches away from such combination. Further, the asserted combination would fail to teach or suggest at least one or more limitations of applicants' claim 2. Therefore, the combination is (a) improper, and (b) fails to establish a *prima facia* case of obviousness required for a valid 35 U.S.C. § 103(a) rejection. Each of these arguments is presented in turn below.

<u>The Asserted Modification Would Render Baura Unsuitable for its Intended Purpose</u>

The Office Action concedes that Baura "fail[s] to disclose the electrical current flow introduced at multiple signal frequencies", and asserts that modifying Baura according to Takehara supplies the limitation(s) missing from Baura. However, processing multiple frequencies, as taught in Takehara, involves methods directly contradicting Baura's express intent.

For example, Baura states an intent to find "an improved method and apparatus for assessing hemodynamic parameters, including cardiac output . . . based on *comparatively simple mathematical operations and non-imaginary operands*, thereby *reducing the burden on associated signal processing hardware* and software", (Col. 3, lines 65-67, col. 4, lines 5-8). Thus, Baura seeks to avoid "complex mathematics (i.e., involve[ing] operands having both real *and imaginary components*), which significantly complicates even simple pattern recognition-related computations", (Col. 3, lines 54-57).

However, Takehara expressly discloses using imaginary operands (i.e., values plotted on an *imaginary* axis - in a function derived from plotting bio-impedances measured in terms of multiple frequencies):

> Following the above multi-frequency bioelectric impedance measurement, the judging apparatus 1 calculates a locus of bioelectrical impedance vectors and a parameters [sic] thereof based on bioelectric impedance values measured for each of a plurality of different frequencies...As a matter of fact, the locus of bioelectrical impedance vectors actually measured is given by an arc determined according to Cole-Cole model. As the calculated locus of bioelectrical impedance is assumed to be in conformity with circular arc shape, the points of bioelectrical impedance $Z_1, Z_2, \ldots, Z_N$ measured in terms

> of frequencies Fi are located as shown in FIG. 6. [L]et us assume that the horizontal axis as a real axis is a X-axis and the vertical axis *as imaginary axis* is a Y-axis in a impedance vector plane. The following correlation function (1) is derived from the Zi (I=1 to n) *plotted on the coordinate system*: $(X-a)^2+(Y-b)^2=r^2$ (Page 4, ¶ [0044]-[0047])(Emphasis provided)

One having ordinary skill in the art will recognize that the operand "Y" in the function represents a value along Takehara's imaginary vertical axis, therefore incorporating an imaginary operand into any calculation utilizing the function.

According to the objectives of Takehara, it is from this very function, and the described calculations utilizing that function and its imaginary operands, that the "combined resistance of the intra-cellular and extra-cellular water resistance . . ., extra-cellular water resistance . . . and intra-cellular water resistance . . ., and therefore the ratio of intra-cellular and extra-cellular water Ri/Re is obtained", (Page 4, ¶ [0051])

Modifying Baura with the multiple frequency bio-impedance measurements of Takehara would render Baura unsuitable for its intended purpose - to "find an improved method and apparatus for assessing hemodynamic parameters, including cardiac output . . . based on *comparatively simple mathematical operations and non-imaginary operands*", (citation supra). This is because Baura expressly defines "complex mathematics" as involving "operands having *both real and imaginary* components", (citation supra), exactly as taught by Takehara. For at least this reason, applicants submit the asserted modification of Baura with the multiple frequency bioimpedance measurements of Takehara is improper, and therefore fails to form the basis for a proper rejection of claim 2 under 35 U.S.C. § 103(a). Applicants request withdrawal of the rejection, and allowance of claim 2.

<u>The Asserted Modification Improperly Changes the Principle of Operation of Baura</u>

Inasmuch as Baura fails to disclose electrical current flow introduced at multiple signal frequencies, Baura also fails to disclose a method for analyzing bio-impedance measurements derived from multiple frequencies to, as the Office Action asserts, "provide a means of more accurately determination any changes in the tissue impedance", (Page 6, § 4).

However, as applicants describe above, the apparatus in Baura is designed in part to "eliminate[e] the contribution from skin and tissue impedance". Therefore, adopting a current injection method to improve the accuracy of determining tissue impedance measurements necessarily changes, and violates, a principle of operation of Baura. Rather than generating bio-impedance measurements which exclude impedance contributions from the skin and tissues, and performing analysis of bio-impedance data from which skin and

tissue impedance is absent, as in Baura, the Office Action asserts the modification will "more accurately determine[e] changes in the tissue impedance".

Notably, Baura's method expressly relies upon *constant* skin and tissue impedances.

> Current flows from each stimulation electrode terminal 1221 through each *constant* skin impedance, Zsk1 or Zsk4, each *constant* body tissue impedance, Zb1 or Zb1, and each *constant* skin impedance, Zsk2 or Zsk3, to each measurement electrode terminal 1223. The voltages at the measurement electrode terminals 1223 are measured and input to a differential amplifier circuit 1227 within the preprocessor 1206 to obtain the differential voltage, VT(t). The desired thoracic impedance, ZT(t), is then obtained using the relationship of Eqn. 30. (Emphasis provided)

Because "the typical impedance associated with a human subject's skin is 2 to 10 times the value of the underlying thoracic impedance" (citation supra) sought by Baura, the asserted combination frustrates rather than achieves Baura's objective by masking the underlying thoracic impedance with changing tissue impedance.

If Baura's method/apparatus receives changing tissue impedances (as asserted by the Office Action) rather than constant impedances as described by Baura, the obtained differential voltage VT(t) will necessarily be affected by the changing rather than constant impedances, further necessarily affecting the obtained thoracic impedance. Thus, the principle of operation of Baura's described method is substantially changed, and neither Baura nor Takehara provide any disclosure describing how to accommodate for those changes.

Further, Baura's method, which includes specifically described apparatus and formulae provided for single-frequency waveform analysis, would need to be changed to accommodate Takehara's multiple frequencies, constituting a change to the operating principle of Baura. For at least this reason as well, the asserted combination renders Baura inoperative, and changes the principle of operation of Baura.

The method for taking multi-frequency measurements in Takehara utilizes a distinct principle of operation from that in Baura, and to a different end. Takehara seeks to determine the *total body water* of a patient, while by contrast, Baura seeks to "eliminate[e] the contribution from skin and tissue impedance" (citation supra) and to determine only the thoracic impedance.

The principle in Takehara is described thusly:

> In this measurement, n different frequencies Fi (i=1, 2, . . . , n and n is a predetermined value) are used and the bioelectric impedance is measured n times for each frequency Fi. Initially, the "i" is set to 1, and the first measurement of bioelectric impedance for frequency F1 is started. (Page 3, ¶

[0039]-[0040]) Next, i is incremented to i+1 (i=i+1) and it is judged whether or not the i exceeds a predetermined value n. If the i exceeds the n, then the overall measurement of the bioelectric impedance is completed. On the other hand, if the i does not exceed the n, the next measurement of the bioelectric impedance for a new frequency will be conducted. (Page 4, ¶ [0043]).

Thus, Takehara describes a predetermined schedule of sequential multi-frequency measurements, generated 'n' times at each frequency. Although "i" can be set equal to one (1), Takehara nevertheless requires multiple frequencies, and therefore multiple measurements. For example, "Said multi-frequency bioelectric impedance measuring device supplies a *plurality of alternating current* of different frequencies to a body of a subject", (Page 1, ¶ [0012]), and "The AC signal generator 20 provides a *plurality of alternating current signals* of different frequencies", (Page 3, ¶ [0036]), and "The device 22 provides the alternating currents of different frequencies *sequentially* at its output terminals 30 and 31", (Page 3, ¶ [0036])(Emphasis provided).

Takehara reinforces this understanding when describing data analysis following the AC current applications; "Following the above multi-frequency bioelectric impedance measurement, the judging apparatus 1 calculates a locus of bioelectrical impedance vectors and a parameters [sic] thereof based on bioelectric impedance *values measured for each of a plurality* of different frequencies", (Page 4, ¶ [0044])(Emphasis provided). Thus, Takehara's method of multiple measurements at different frequencies is suitable for Takehara's bio-impedance locus plotting analysis method.

By contrast, Baura describes that "the method of providing treatment 1300 generally comprises . . . applying *a constant AC waveform* to the stimulation terminal(s), and measuring the resultant voltage at the measurement terminal(s)", (Col. 22, lines 32-33, 43-45)(Emphasis provided). Baura does not describe repeated measurements, but rather repeatedly describes only a "constant AC waveform". For example, "In operation, the apparatus 1200 generates an effectively *constant current* (via the current source 1204) which is applied to certain ones of the terminal(s) 1221 of the electrodes 1202", (Col. 20, lines 8-11)(Emphasis provided). One having ordinary skill in the art will recognize that Baura's constant current is necessary to capture numerous heart beats in an output waveform, as "The time interval between the R waves is also used to calculate the heart rate", (Col. 4, lines 66-67).

Thus, Baura's method of applying a 'constant AD waveform' underlies Baura's analytical method of "waveform analysis", a central principle of Baura's method and apparatus. As Baura states, "Impedance cardiography . . . *requires* recording of the subject's

electrocardiogram (ECG) *in conjunction with the thoracic impedance waveform,*" and "processing of the impedance waveform *for hemodynamic analysis* requires the use of ECG fiducial points as landmarks", (citation supra).

The distinct methods of Takehara and Baura are specifically designed to enable their respective and disparate analytical principles and ends, and modifying Baura with the multiple frequencies of Takehara would alter the principle of operation of Baura. The Office Action and the references provide no guidance for reconciling the described conflicting objectives, consequences, and principles of the references. For at least this reason, one having ordinary skill in the art would not be motivated to modify Baura as asserted and described in the Office Action, and applicants submit the asserted modification of Baura with the multiple frequency bioimpedance measurements of Takehara is improper.

Baura Teaches Away from the Asserted Modification

As discussed above regarding the rejection of independent claim 1, Baura describes that "the typical impedance associated with a human subject's skin is 2 to 10 times the value of the underlying thoracic impedance". Therefore, the apparatus and method of Baura is specifically designed to "eliminat[e] the contribution from skin and tissue impedance", and to obtain "the desired thoracic impedance", (citations supra).

As also discussed above, the asserted motivation of "provid[ing] a means of more accurately determining any changes in the tissue impedance" (Office Action, page 6, § 4) stands directly contrary to Baura's express intent to eliminate such influences. For at least this reason Baura strongly teaches away from the combination, and exposes the fallacy of the Office Action's asserted motivation to combine the references.

Further, as discussed above, Baura intends to solve problems associated with the prior art by providing an "improved method and apparatus . . . based on comparatively simple mathematical operations and non-imaginary operands". Inasmuch as Takehara's method expressly utilizes imaginary operands, as described above, Baura expressly teaches away from the methods of Takehara, which Takehara requires to analyze the plurality of multi-frequency impedance measurements.

The Asserted Modification Would Fail to Teach or Suggest at Least One or More Limitations of Applicants' Claim

In View of Takehara

As also discussed above regarding the rejection of independent claim 1, simply modifying the apparatus and method of Baura as asserted in the Office Action to "include the use of multi-frequency currents" fails to teach or suggest the limitation(s) recited in applicants' independent claim 1, which are likewise incorporated in claim 2.

Because Baura "eliminate[s] the contribution from skin and tissue impedance", and obtains only "the desired thoracic impedance", Baura fails to "derive[e] . . . two or more electrical bio-impedance values *indicating the electrical bio-impedance of body tissues and* fluids within a region of the anatomical space; *and analyz[e] the two or more electrical bio-impedance values*" as recited in applicants' independent claim 1. It logically follows that one doesn't analyze what one eliminates.

As discussed above, Baura expressly teaches that skin and tissue impedance values greatly exceed the thoracic impedance values, and therefore impede attempts to accurately determine Baura's "desired thoracic impedance". To the extent that Baura may not successfully eliminate *all* impedance contributions of the 'skin and tissues', which applicants do not concede or assert, asserting that one having ordinary skill in the art would understand Baura to teach deriving and analyzing the bio-impedance of tissue would constitute factual and/or legal error. Baura can not be held up as teaching that which it expressly seeks to and is designed to avoid.

Improperly combining the multiple frequency measurements of Takehara does nothing to remedy the intentional failure of Baura to derive and analysis tissue bio-impedance values. Rather, the apparatus and method of Baura would negate any 'benefit' provided by improperly combining the references as asserted, by eliminating the supposedly "more accurat[e] determin[ation of] any changes in tissue impedance as it is designed to do.

For at least these reasons, applicants respectfully submit that the asserted modification of Baura in view of Takehara would fail to teach or suggest one or more limitations of applicants' claim 2, which depends from and includes the distinct limitation(s) of independent claim 1.

In View of Doung

The Office Action concedes that the combined references of "Baura and Takehara fail to disclose analyzing the acquired data through the use of Fourier transform and data reduction", (Page 6, § 4), but asserts that Duong teaches the limitation(s) not provided by Baura and Takehara. However, the assertion constitutes factual error for at least the reason that the asserted modification fails to disclose one or more limitations recited in applicants' claim 2.

Specifically, the Office Action cites Column 89, lines 1-21 as support for Duong disclosing analyzing acquired data through the use of data reduction. One having ordinary skill in the art will recognize the error of the assertion.

According to the cited section:

> "Curve fitting and peak recognition can be achieved by modeling the data . . . using linear models such as the Least squares method . . . and Chisquare fitting (Bevington et al., *Data Reduction* and Error Analysis for the Physical Sciences, N.Y. McGraw Hill (1969) . . .) or nonlinear models such as Levenberg-Marquardt . . . and other nonlinear least-squares . . . methods. (Col. 89, lines 1-21)

Thus, the Office Action appears to suggest that because the words "Data Reduction" appear in the title of a publication cited in the reference, that the reference teaches the limitation of 'data reduction'. One having ordinary skill in the art would recognize that the asserted reasoning is without basis.

The publication cited in the reference is titled Data Reduction *and* Error Analysis for the Physical Sciences (emphasis provided), identifying two distinct topics; Data Reduction, and Error Analysis. However, what the reference expressly describes is *Chisquare fitting*, stating that it is a 'linear data modeling' method. In particular, those having skill in the art will recognize that Chisquare fitting is a method for 'curve fitting', and is used for *error analysis*, not data reduction. Therefore, it relates only to the second topic of the publication, 'Error Analysis'. Quite simply, the reference says absolutely nothing about data reduction, and does not rely upon or employ the publication for any purpose related to *data reduction*. 'The phrase 'Data Reduction' simply happens to be in the title of a resource cited for an entirely separate purpose, and the extensive 110-column disclosure of Duong completely fails to disclose applicants' recited limitation wherein "the analyzing of the electrical bio-impedance values includes Fourier analysis *and data reduction*", (Emphasis provided).

For any one of and/or any combination of the reasons provided above, applicants respectfully submit that the combined references fail to disclose at least the limitations of applicants' claim 2. Therefore, applicants respectfully submit that claim 2 is allowable over the references, either alone or when combined, and request withdrawal of the 35 U.S.C. § 103(a) rejection from claim 2.

Claim Rejections – 35 U.S.C. § 103

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baura et al (USPN 6,561,986) as applied to claim 12 above, and further in view of Carter et al (USPN 5,674,264)(Carter).

The Office Action concedes that Baura "fail[s] to disclose electrode selector switch circuitry responsive to . . . select which ones of the multiple electrodes introduce the electrical current flow and which ones of the multiple electrodes define measurement vectors relating to the electrical voltages produced". The Office Action further asserts that modifying Baura according to Carter supplies the limitation(s) missing from Baura.

However, as described above regarding the 35 U.S.C. § 102(e) rejection of claim 12, Baura fails to disclose limitations of amended independent claim 12 from which claims 18-21 depend, and which distinct limitations claims 18-21 incorporate. For example, Baura fails to disclose:

> processor circuitry programmed with instructions configured when executed to . . . *compute from each of different pairs of the injection and measurement vectors an electrical bio-impedance value that characterizes the electrical bio-impedance of the mammalian tissue and fluids* in a region of an anatomical space, *and to analyze the electrical bio-impedance values* and identify characteristics indicating fluid movement, accumulation, or depletion affecting the region. (Emphasis provided)

Carter fails to compensate for the teaching absent from Baura, and therefore the combined references of Baura and Carter likewise fail to disclose one or more limitations of applicants' claims 18-21. For at least this reason, applicants respectfully submit that claims 18-21 are allowable over the asserted combination of references, and request withdrawal of the 35 U.S.C. § 103(a) rejections therefrom.

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CONCLUSION

Accordingly, applicants request entry of the above amendment and consideration of the application on the merits. The Examiner is encouraged to telephone the undersigned at (503) 226-8495 if it appears that an interview would be helpful in advancing the case.

Respectfully submitted,

Patrick D. Boyd
Reg. No. 32,496
Ater Wynne LLP
222 SW Columbia, Suite 1800
Portland, Oregon 97201

Customer No. 35940

I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via facsimile number (571) 273-8300 on March 5, 2008.

NAME